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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/523,617 | 01/06/2006 | Jillian Cornish | 11752-010US1 | 1861 |
| 69713 7590 09/22/2008 OCCHIUTI ROHLICEK & TSAO, LLP 10 FAWCETT STREET CAMBRIDGE, MA 02138 | | | | |
| EXAMINER BRADLEY, CHRISTINA | | | | |
| ART UNIT | | PAPER NUMBER | | |
| 1654 | | | | |
| NOTIFICATION DATE | | DELIVERY MODE | | |
| 09/22/2008 | | ELECTRONIC | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

INFO@ORTPATENT.COM

Office Action Summary

Application No.

10/523,617

Applicant(s)

CORNISH ET AL.

Examiner

Christina Marchetti Bradley

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 June 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 11, 13, 23, 25, 35, 54, 55, 57, 58, 60 and 61 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 11, 13, 23, 25, 35, 54, 55, 57, 58, 60 and 61 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsman's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Status of Claims

1. Claims 1, 11, 13, 23, 25, 35, 54, 55, 57, 58, 60 and 61 are pending. Claims 12, 24, 36, 53, 56 and 59 were cancelled in the amendment filed 06/12/2008.

Sequence Compliance

2. The objection to the application regarding sequence compliance is withdrawn in light of the amendment filed 06/12/2008.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. The rejection of claims 1, 11-13, 23-25, 35 and 36 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement and enablement requirement, is withdrawn in light of the amendment filed 06/12/2008.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1, 11, 13, 23, 25, 35, 54, 55, 57, 58, 60 and 61 are rejected under 35 U.S.C. 102(b) as being anticipated by Cooper *et al.* (WO 00/78805). Cooper *et al.* teach a method of therapeutically or prophylactically treating a patient by administering an effective

amount of preptin or an analog thereof (claim 33). Cooper *et al.* recite peptides that are 100% identical to instant SEQ ID NOs: 1, 2 and 3 (claims 3-5) as examples of preptins suitable for administration. In addition, Cooper *et al.* teach the following genus of peptides as examples of preptin or preptin analogs:

DVST**123**VLPD**4**FPYPVGKFF**56**DTW**7**QS**89**RL

wherein 1 is S or P; 2 is Q or P; 3 is A or T; 4 is D or N; 5 is Q or K; 6 is Y or F; 7 is R or K; 8 is A or T; and 9 is G or Q (claim 2). Species within this genus include peptides comprising SEQ ID NO: 1, 2 or 3 with one conservative amino acid substitution that are 95% identical to SEQ ID NOs: 1, 2 or 3.

Cooper *et al.* do not explicitly teach that the administration of preptin is for the purpose of treating a bone condition associated with breakdown of bone tissue or bone loss, increasing or maintaining bone density, or stimulating osteoblast growth or inhibiting osteoblast apoptosis, or that the peptide promotes osteoblast proliferation. The patient population taught by Cooper *et al.* is not limited and can include any patient. Cooper *et al.* anticipate claims 1, 11, 13, 23, 25, 35, 54, 55, 57, 58, 60 and 61 because all patients experience the breakdown of bone tissue or bone loss as a natural part of aging, as evidenced by Cosman (http://bcbsma.medscape.com/viewprogram/4011_pnt) which teaches on page 5 that “the net loss of bone that occurs with aging is a universal phenomenon.” Therefore, all patients are in need of increasing or maintaining bone density or stimulating osteoblast growth or inhibiting osteoblast apoptosis, in order to prevent serious bone conditions such as osteoporosis, as evidenced by Cosman. Because the prior art teaches the administration of identical peptides to the identical

patient population as the instantly claimed methods, all functional effects recited in the instant claim are inherent to the prior art.

Allowable Subject Matter

7. Claims 54, 55, 57, 58, 60 and 61, which were previously indicted as objected to but allowable if rewritten in independent form, are now rejected.

Conclusion

8. No claims are allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christina Marchetti Bradley whose telephone number is (571)272-9044. The examiner can normally be reached on Monday, Tuesday and Thursday, 8 A.M. to 5:30 P.M.

10. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

11. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Cecilia Tsang/
Supervisory Patent Examiner, Art Unit 1654

/Christina Marchetti Bradley/
Examiner, Art Unit 1654